

REMARKS

I. Statement

A. On or About April 27, 2006

On or about April 27, 2006, Applicant's representatives, Victoria Silcott and Stanislaus Aksman, were contacted by the Examiner to discuss the Supplemental Response filed on March 13, 2006.

The Examiner questioned support for the elasticity module in claims 45-47 and 68-70. Applicant's representatives pointed out that support exists in the provisional application, to which this application claims the benefit and which was incorporated by reference. Applicant's representatives suggested that the specification may be amended to include the relevant disclosure from the provisional application.

The Examiner also questioned the support for the word "backbone" as used in claims 27 and 52. Applicant's representatives submitted that the empirical formula and the chemical structure on page 9 of the specification would clearly indicate to a person of ordinary skill in the art the meaning of the term "backbone". The Examiner did not find that persuasive and suggested that the claims be amended to state that the polyacrylamide has the empirical formula set forth at page 9.

The Examiner also suggested that claims 27 and 52 be amended to include the limitation "at least 95% pyrogen-free water or saline solution" and that claims 30, 41, 42, 55, 65 and 66 be canceled. In addition, the Examiner suggested amendments of claims 49 and 72 to state: "saline solution".

B. May 9 and 12, 2006

Applicant's representatives had two short, follow-up telephonic interviews with the Examiner on May 9 and May 12, 2006. Applicant's representatives offered evidence showing that the term "backbone" was known to one of ordinary skill in the art at the time the application was filed. The Examiner confirmed that the claims would still be rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to meet the written description requirement based on the presence of the term "backbone". Instead, the Examiner indicated that he could make the

amendments he suggested during the interview held on or about April 27 to prevent such a rejection.

C. July 28, 2006

On July 28, 2006, Applicant's representative, Stanislaus Aksman, held a telephonic interview with the Examiner. Applicant's representative proposed an amendment to claims 27 and 52 to remove the term "backbone" and to recite that the polyacrylamide consists essentially of a cross-linked polymerized acrylamide. The Examiner said that such an amendment will not overcome the rejection of the claims under 35 U.S.C. § 112, first paragraph, as stated in the June 1, 2006 Office Action, because the cross-linker is to be identified as methylene- bisacrylamide. Applicant's representative said he would take that suggestion under advisement.

Applicant's representative stated that, in the interest of expediting prosecution, claims 45-47, 68-70, 28 and 53 would be canceled.

In addition, Applicant's representative suggested amending claims 27 and 52 to recite that the polymer hydrogel comprises at least 95% by weight pyrogen-free water or a saline solution. The Examiner agreed that this amendment would obviate the rejection of claims 27-33, 35-42 and 44-74 under 35 U.S.C. § 112, first paragraph.

Applicant's representative also suggested amending claims 50 and 73 to recite that the prosthetic device is stored in a syringe. The Examiner agreed that this amendment would overcome the rejection of claims 50, 51, 73 and 74 under 35 U.S.C. § 112, second paragraph.

D. August 9, 2006

On August 9, 2006, Applicant's representatives, Ms. Silcott and Mr. Aksman, held a telephonic interview with the Examiner regarding an alternative amendment to that suggested by the Examiner on July 28th. The proposed amendment excluded the empirical formula from page 9 of the specification, but instead, recited that the polyacrylamide consists essentially of a cross-linked polymerized acrylamide and that the cross-linking comprises the use of methylene- bisacrylamide. The Examiner advised that such an amendment would also be acceptable and would overcome the rejection of claims 27 and 52 under 35 U.S.C. § 112, first paragraph.

Applicant's representatives also suggested adding two new claims dependent from claims 27 and 52 reciting that the polymer hydrogel comprises the empirical formula at page 9, lines 24-

25 of the specification. The Examiner agreed that the two new dependent claims would be acceptable as well.

II. Amendment

Reconsideration of the rejections in the Application is respectfully requested. Upon entry of the foregoing amendment, claims 27, 29, 31-33, 35-40, 44, 48-52, 54, 56-64, 67, and 71-76 will be pending. Claims 27-33, 35-42, and 44-74 stand rejected. Claims 28, 30, 41, 42, 45-47, 53, 55, 65, 66, and 68-70 are canceled. Claims 27, 49, 50, 52, 72, and 73 are amended. New claims 75 and 76 are added.

Applicant respectfully requests entry of the above amendment and submits that the amendment does not introduce new matter. Support for the amendment to the claims and for the new claims can be found throughout the specification (considered as a whole) and in the claims as originally filed. In particular, support for the amendment to claims 27 and 52 can be found, *inter alia*, in the specification at page 9, lines 20-23 and page 10, lines 31-34 and in the claims as originally filed. Support for the amendment to claims 49 and 72 can be found, *inter alia*, in the specification at page 9, lines 20-23 and in the claims as originally filed. Support for the amendment to claims 50 and 73 can be found, *inter alia*, in the specification at page 8, lines 21-22. Support for new claims 75 and 76 can be found, *inter alia*, in the specification at page 9, lines 24-25.

Based on the above amendments, the interviews, and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

III. Claim Rejections Under 35 U.S.C. § 112, ¶ 1

Claims 27-33, 35-42, and 44-74 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. *See* Office Action, p. 2. Applicant respectfully traverses this rejection.

The Office Action stated that claims 27 and 52 refer to a polyacrylamide which has a backbone consisting essentially of the formula $(C_3H_5NO)_x$ but that the term "backbone" does not appear anywhere in the original specification. In addition, the Office Action stated, "[A]pplicant is seeking to broaden the invention disclosed since the backbone may be attached to a different hydrocarbon chain." *See* Office Action, p. 3.

Applicant respectfully disagrees. First, the term "backbone" is well understood by one of ordinary skill in the art. Second, the transition phrase "consisting essentially of," in combination with the formula recited, and the further recitation of "wherein said polyacrylamide is made by a method comprising combining acrylamide and methylene bis-acrylamide," adequately describes the claimed invention. For at least these reasons, the rejection is misplaced.

However, in order to expedite prosecution, claims 27 and 52 have been amended. Applicant respectfully submits that the amended claims overcome the rejection of claims 27-33, 35-42, and 44-74 under 35 U.S.C. § 112, first paragraph, as indicated by the Examiner in the interview held on August 9, 2006. Accordingly, Applicant respectfully requests that the rejection be reconsidered and withdrawn.

Claims 45-47 and 68-70 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to meet the written description requirement for adding new matter. *See* Office Action, p. 3. Claims 45-47 and 68-70 have been canceled. Therefore, Applicant respectfully submits that this rejection is moot and respectfully requests that the rejection be withdrawn.

Claims 27-33, 35-42, and 44-74 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to meet the enablement requirement. The Office Action stated, "[T]he specification, while being enabling for a hydrogel as set out in claims 27 and 52 which comprise at least 95% by weight pyrogen-free water or saline solution, does not reasonably provide enablement for a hydrogel without this major constituent [*sic*]." P. 3. Claims 27 and 52 have been amended to include the limitation "at least 95% by weight pyrogen-free water or a saline solution." Therefore, Applicant respectfully submits that this rejection is moot and respectfully requests that the rejection be withdrawn.

Claims 28 and 52 are also rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to meet the enablement requirement "because the specification, while being enabling for a hydrogel with at least 0.5% by weight and less than 3.5% polyacrylamide, does not reasonably provide enablement for a hydrogel having all % polyacrylamide above 3.5." Office Action, p. 4.

As confirmed with the Examiner in the interview held on July 28, 2006, there was a typographical error in the Office Action. Claim 53, as opposed to claim 52, is rejected under 35 U.S.C. § 112, first paragraph. Claims 28 and 53 have been canceled. Therefore, Applicant respectfully submits that this rejection is moot and respectfully requests that the rejection be withdrawn.

III. Claim Rejections Under 35 U.S.C. § 112, ¶ 2

Claims 50, 5, 73, and 74 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Office Action stated, "Claims 50 and 73 are indefinite in that it refers to a syringe as a prosthetic device. A syringe may be used to administer the hydrogel which becomes the prosthetic device or endoprosthesis, but it is not itself a prosthetic device." Pp. 4-5.

As confirmed with the Examiner in the interview held on July 28, 2006, there was a typographical error in the Office Action. Claim 51, as opposed to claim 5, is rejected under 35 U.S.C. § 112, second paragraph. Claims 50 and 73 have been amended to recite "wherein said prosthetic device is stored in a syringe." Applicant respectfully submits that this amendment overcomes the rejection of claims 50, 51, 73, and 74 under 35 U.S.C. § 112, second paragraph, as indicated by the Examiner in the interview held on July 28, 2006. Accordingly, Applicant respectfully requests that the rejection be reconsidered and withdrawn.

CONCLUSION

For at least the reasons stated above, claims 27, 29, 31-33, 35-40, 44, 48-52, 54, 56-64, 67, and 71-76 are in condition for allowance. Accordingly, Applicant respectfully requests that the Application be allowed and passed to issue.

In the event any outstanding issues remain, Applicant would appreciate the courtesy of a telephone call to Applicant's undersigned representative to resolve such issues in an expeditious manner.

Respectfully submitted,

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